

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION
(PCT Article 36 and Rule 70)

REC'D 29 DEC 2000

REPORT **PCT**

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Applicant's or agent's file reference 40135146	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU99/00665	International Filing Date (day/month/year) 16 August 1999	Priority Date (day/month/year) 14 August 1998
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61B 3/02 A61F 9/007		
Applicant Q-VIS LIMITED et al		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of 6 sheets, including this cover sheet. <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of 4 sheet(s).
3.	This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input checked="" type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application

Date of submission of the demand 2 March 2000	Date of completion of the report 12 December 2000
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer ROSEMARY LONGSTAFF Telephone No. (02) 6283 2637

I. Basis of the report**1. With regard to the elements of the international application:***

- ☐ the international application as originally filed.
- ☒ the description, pages **1-2, 5-10**, as originally filed,
pages , filed with the demand,
pages **3-4**, received on **11 October 2000** with the letter of
- ☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages **11-12**, received on **11 October 2000** with the letter of
- ☒ the drawings, pages **1-2**, as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-20 are directed to a fixation target for limiting the rotation of the eye. It is considered that the at the least one elongate component having a fixed orientation comprises a first "special technical feature".

2. Claims 21-41 are directed to an apparatus for supplying visual feedback to an operator during refractive surgery of an eye. It is considered that the means for viewing the eye and the information display simultaneously comprises a second "special technical feature".

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.
- ☐ the parts relating to claims Nos.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-20, 23-24, 28, 35, 37	YES
	Claims 21-22, 25-27, 29-34, 36, 38-41	NO
Inventive step (IS)	Claims 1-20, 23, 35	YES
	Claims 21-22, 24-34, 36-41	NO
Industrial applicability (IA)	Claims 1-41	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

D1 US 4993825

D2 US 5549597

D3 US 5135299

D4 US 4870964

D5 US 4678297

D6 WO 98/00078

NOVELTY

Claims 21-22, 25-27, 29-34, 36 and 38-41 are not novel over D3.

Although a "fixation target means" is not explicitly disclosed, obviously, to enable a surgical operation to be performed on the eye, the eye needs to be kept still.. The illuminating light emitted from light source (55) would provide such a target.

All other features of these claims are disclosed in this document.

Claims 21-22, 26, 29-34, 36 and 38-41 are not novel over D4.

A "fixation target means" is provided by the display head (34a). All other features of these claims are disclosed in this document, the eye itself providing a "screen means".

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box VINVENTIVE STEP

Claim 24 does not provide an inventive step over D3 or D4 alone or when either of these documents is combined with either D1 or D2.

Laser surgery on the eye is well-known. To combine the visual feedback features disclosed in D3 or D4 with laser surgery does not require any ingenuity involving an inventive step.

Claims 28 and 37 do not provide an inventive step over either D3 or D4 in combination with either D5 or D6. An alert signal to warn of misalignment of the eye is disclosed in D5 (column 5, lines 14-31) and D6 (claims 5 and 6). It would be obvious to combine this feature with those of D3 or D4 to provide all the features of claims 28 and 37.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The invention is not clearly defined, since the features that define the invention in its broadest sense are not apparent. The "Summary of the Invention" gives two "aspects" of the invention, but there are no unifying features between these aspects.

Claims

1 **[Am nd d]** A fixation apparatus for limiting the rotation of the ocular globe of an eye, to facilitate alignment of an instrument with the axis of astigmatism of the eye, including:

5 fixation target means for locating in the field of view of said eye so that said eye may fixate on said target;

 wherein said fixation target means includes or consists of at least one elongate component having a fixed orientation.

2 Apparatus according to claim 1 wherein said fixation target
10 means includes or consists of at least two intersecting, substantially mutually perpendicular elongate components.

3 Apparatus according to claim 2 wherein said fixation target means consists substantially of a cross.

4 Apparatus according to claim 2 or 3 wherein one of the at least
15 two elongate components is longer than the other.

5 Apparatus according to claim 1 wherein said fixation target means includes more than two elongate components arranged as a grid.

6 Apparatus according to any one of claims 1 to 5 wherein said fixation target means is a light emitting means.

20 7 Apparatus according to claim 6 wherein the or each said elongate component is defined by said light emitting means.

8 Apparatus according to claim 6 or 7, wherein said light emitting means includes a plurality of light emitting diodes arranged in a respective linear array to define the or each said elongate component.

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9 Apparatus according to claim 8, further including a printed circuit board (PCB) on which the light emitting diodes are mounted.

10 Apparatus according to any one of claims 6 to 9, further including means to strobe said light emitting means.

5 11 Laser surgery apparatus incorporating patient observable fixation apparatus according to any one of claims 1 to 10.

12 Laser surgery apparatus according to claim 11, wherein said fixation target means is disposed in a patient observable position on a surgical microscope of said laser surgery apparatus.

10 13 Laser surgery apparatus according to claim 12 wherein said at least one elongate component is arranged in a "vertical" orientation on said surgical microscope.

15 14 **[Amended]** A method for limiting the rotation of the ocular globe of an eye to facilitate alignment of an instrument with the axis of astigmatism of the eye, including providing fixation target means in a field of view of said eye so that said eye may fixate on said target, wherein said fixation target means includes or consists of one elongate component having a fixed orientation.

20 15 A method according to claim 14, wherein said fixation target means includes or consists of at least two intersecting, substantially mutually perpendicular elongate components.

16 A method according to claim 15, wherein said fixation target means consists substantially of a cross.

17 A method according to claim 14, wherein said fixation target means includes more than two components arranged as a grid.

25 18 A method according to anyone of claims 14 to 17, including providing said fixation target means by way of light emitting means.

Corresponding to the patient fixation apparatus is the apparatus used by the surgeon to view and assess the extent of fixation and the alignment of the laser beam. The surgeon views this display when looking down the surgical microscope. Current technology provides a display including a graticule or crosshair. A He-Ne
5 beam is sometimes provided for aiming the surgical beam.

US Patent 4,870,964 provides a head-up display for use with an operating microscope during phaco-emulsification procedures. This apparatus allows the operating surgeon to view information about the status of the patient, the eye and operating equipment, such as vacuum pressure, without removing their gaze from
10 the operating field. It does so by projecting light onto the operating field of the eye and conditioning the reflections from the cornea so that interpretable images may be viewed by the surgeon as they look down the microscope. US Patent 5,135,299 describes a similar operating microscope featuring a head-up display, produced by reflecting operational information from the scleral portion of the eye.

15 It is an object of the present invention, in at least one aspect, to provide an eye fixation method and apparatus that is simple and reliable, and involves minimal expectation of the patient. For particular applications, it is further preferred that the arrangement reduces the angular rotation of the ocular globe to facilitate alignment of an instrument with the axis of astigmatism.

20 It is an object of another aspect of the present invention to provide a surgical visual feedback method and apparatus that provides increased information to the surgeon or operator.

Summary of the Invention

According, therefore, to a first aspect of the present invention, there is
25 provided a method for limiting the rotation of the ocular globe of an eye to facilitate alignment of an instrument with the axis of astigmatism of the eye. The method includes providing fixation target means in the field of view of the eye so that the eye may fixate on the target. The fixation target means includes or consists of at least one elongate component having a fixed orientation.

Preferably the method includes providing the fixation target means by way of light emitting means. Preferably, the light emitting means is strobed.

The present invention also provides, in its first aspect, a fixation apparatus that limits rotation of the ocular globe of an eye, to facilitate alignment of an instrument with the axis of astigmatism of the eye. The apparatus includes fixation target means for locating in the field of view of the eye so that the eye may fixate on the target. The fixation target means includes or consists of at least one elongate component having a fixed orientation.

Preferably, said fixation target means includes or consists of at least two intersecting substantially mutually perpendicular elongate components. The fixation target means may consist substantially of a cross, and/or it may include more than two elongate components arranged as a grid. The fixation target means preferably has a fixed orientation.

The fixation target means may be a light emitting means. Moreover, the or each elongate component may be defined by the light emitting means.

Preferably, the light emitting means includes a plurality of light emitting diodes (LEDs) arranged in a respective linear array to define the or each elongate component.

Preferably the apparatus includes a printed circuit board (PCB) on which the LEDs are mounted.

Preferably the apparatus is controllable to strobe the light emitting means.

The apparatus may include a pulsable power supply to strobe the light emitting means.

In its first aspect, the invention extends to laser surgery apparatus incorporating patent observable fixation apparatus as described above.

In a second aspect of the present invention there is provided a method for